

NOV 13 1998

**SECTION 12.0**  
**510(k) Summary**

Company Name: Sterngold ImplaMed  
Address: 23 Frank Mossberg Drive  
Attleboro, MA 02703  
Registration #: 2921595  
Contact Person: Chad Patterson  
Date Prepared: Friday, October 23, 1998

Classification Name: Endosseous Implant (DZE)  
Common Name: Wide Platform Screw Implant, Wide Diameter,  
Implant Fixture  
Trade Name: Sterngold ImplaMed Hex Screw Implant,  
Wide Platform Screw Implant

**Device Description**

Device consists of titanium screws, and titanium alloy prosthetics, brass and stainless steel restorative components, and stainless steel and titanium alloy surgical instruments.

**Intended Use**

Device can be used in dental implant applications for oral rehabilitation of edentulous and partially dentate patients in the maxillae and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures.

**Technological Characteristics**

The modified devices utilize wide diameter titanium screws and related prosthetics and instrumentation. Materials are identical to those currently used in our predicate devices. The wide platform screw products are compatible with current Sterngold ImplaMed installation instrumentation and prosthetic procedures.

**Comparative Products**

Sterngold ImplaMed currently has permission to market Titanium Screw Implants, Titanium and Titanium alloy prosthetics, and stainless steel instrumentation. Wide platform and diameter screw implants are currently marketed by several companies. Sterngold ImplaMed Wide Platform implants prosthetics and instruments are substantially equivalent to these marketed devices in design, materials, performance and intended use.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Chad Patterson  
Director of Product Development  
SternGold ImplaMed  
23 Frank Mossberg Drive  
Attleboro, Massachusetts 02703-0967

Re: K983786  
Trade Name: SternGold ImplaMed Wide Platform Dental  
Implants and Related Prosthetics and Instrumentation  
Regulatory Class: III  
Product Code: DZE  
Dated: October 23, 1998  
Received: October 27, 1998

Dear Mr. Patterson:

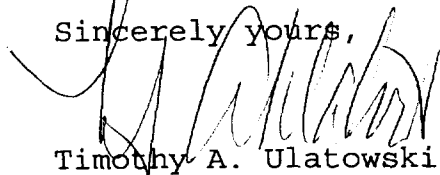
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

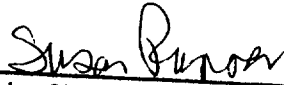
Enclosure

**SECTION 10.0**  
**Indications for Use**

**Indications:**

The Sterngold ImplaMed Implant can be used in dental implant applications for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures.

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number 1C983786